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EXAMINER

ZHOU, S

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/601,561

Applicant(s)

SCHNEIDER ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 12, 15-33, 43, and 64-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-14, 34-42, and 44-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-65 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicants' election, with traverse, of Species A, drawn to compositions and methods using same comprising nucleic acids having two protein binding sites, in Papers No. 6, filed 5/14/01, is acknowledged. Applicants traverse that a search for the 2 sites nucleic acids will include three sites nucleic acids and thus no search burden is imposed if the two species are examined together. This is not found persuasive because the argument is not directed to the reason of the separate examination of the species and no specific argument is provided. Furthermore, search of each species would require independent considerations which would require the examiner to focus on different features (for example different arrangement of the binding sites in the nucleic acids for Species B) and entail differently structured word searches for both patent and non-patent literature for each of the two Species.

Applicants also argue that SEQ ID NOs: 1-3 contain the same protein binding sites and request that they be examined together. Applicants' request is granted and SEQ ID NOs: 1-3 are co-examined.

Applicants state that claims 1-13, 33-44, and 46-62 read on the elected species, i.e. Species A, directed to nucleic acids having 2 protein binding sites. However, it is noted that claims 12, 33 and 43 are inadvertently classified in Species A although they are actually directed to nucleic acids containing 3 protein binding sites. On the other hand, since SEQ ID Nos: 1-3 are examined together, claims 14, 45 and 63, which are

directed to nucleic acids containing 2 protein binding sites but involve SEQ ID NOs: 2 and 3, should also be included in the elected species. In summary, the traversal arguments are non-persuasive for reasons as given above except for now permitting co-examination of SEQ ID NOs: 1-3. The modified restriction requirement is still deemed proper and is, therefore, made FINAL.

Accordingly, claims 1-11, 13-14, 34-42, and 44-63 are directed to the elected subject matter, and are examined, and claims 12, 15-33, 43, and 64-65 are presently withdrawn from further consideration as being drawn to non-elected invention.

### ***Specification***

The specification is objected to because of the following:

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The figures are objected to because the specification refers to Figures 8a, 8b and 8c, however, there are no such figures but Figure 8 are provided.

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at page 7 and elsewhere. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP ' 608.01.

Appropriate correction is required.

### ***Claim Rejections-35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1-11, 13-14, 34-42, and 44-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "encodes" in claims 1, 15, 34, 51, and claims that are dependent from these claims is confusing. It is not clear what is meant by "encodes". One interpretation is that the protein binding sites encoded by the nucleic acid sequences are still nucleic acids which can be bound by proteins. Another interpretation is that the protein binding sites encoded by the nucleic acid sequences are actually sites on a protein that can be bound by another protein. Thus, the metes and bounds of the claims is not clear.

The term "composition" in claims 2-11, 13-14, and 63 lacks clear antecedent basis and thus the metes and bounds of the claims are not clear.

The phrase "the difference in strength" in claims 11, 42 and 61 lacks clear antecedent basis and thus the metes and bounds of the claims are unclear.

Claim 34 and its dependent claims are drawn to "a composition for the storage of binary information". Claim 51 and its dependent claims are drawn to methods of storing information. However, it is not clear from the claim language what constitutes the information and where it is stored.

***Claim Rejections-35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 13-14, 34-42, and 44-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darnell et al. (Molecular Cell Biology, 1990, published by Scientific American Books) in view of Hengen et al. (Nucleic Acids Research, 1997, Vol. 25, No. 24, pages 4997-5002).

Darnell et al. disclose a cellular system or composition comprising a double stranded nucleic acid (DNA) molecule of more than 3 base pairs in length having 2 binding sites, I<sub>1</sub> and I<sub>2</sub>, and a nucleic acid binding protein AraC, which, in the absence of

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arabinose, binds to  $I_1$ , but not  $I_2$  (see pages 243-244). Darnell et al. motivating study other DNA binding proteins and their respective binding sites (pages 254-255).

Hengen et al. disclose a composition comprising a double stranded nucleic acids (DNA) of more than 3 base pairs in length having multiple Fis binding sites including 2 within the nrd promoter which are 11 base pairs apart, and 2 within the cin gene which are 7 base pairs apart, and a protein Fis which can specifically bind to the Fis binding sites on the nucleic acids (see page 4999, right column and Figure 5, and page 5001). The two Fis sites within the nrd promoter, when separated, are individually able to bind Fis protein (page 5001). These natural Fis sites are at least 2.4 bits in strength and the difference in strength between the two sites is at least 0 bits, as determined by individual information theory (page 4999, Figure 5, and page 5001, left column), and are the same in that they all can specifically bind to the Fis protein. Some of them have identical nucleotide sequences and some very similar (see page 4995, Figure 1).

Methods of performing such binding assays including binding a protein to a nucleic acids would have been well-known in the art and Hengen et al. disclose detailed procedures of doing same for Fis protein and nucleic acids containing Fis binding sites (Materials and Methods, pages 4994-4996, and legends for Figures 7 and 8).

These references do not explicitly disclose protein binding sites with the exact nucleotide sequences of the instant SEQ ID NOs: 1-3, as required in the instant claims. However, Hengen et al. do motivate synthesis of artificial nucleic acids containing different Fis sites with different spacing to test their binding to the Fis protein (see page 4999, Figure 5, and page 5001, left column). Furthermore, since the essential parts of

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sequences of the instant SEQ ID NOs: 1-3 are Fis binding sites as disclosed by Hengen et al. with different spacing between the Fis sites, 11 base pairs in the case of SEQ ID NO:2 and 7 in SEQ ID NO:3, such artificial nucleic acids, which are very similar to those artificial oligonucleotides disclosed by Hengen et al., would have been obvious to one of ordinary skill in the art and a reasonable success of synthesizing such nucleic acids would have been highly expected.

These references do not explicitly disclose nucleic acids with Tus or EF-tu binding sites as required in the instant claims. However, Hengen et al. do suggest and motivate studying other DNA binding proteins and their binding sites by stating that the model used in their study "can be applied to any nucleic acid binding interactions(see page 5001, right column). Since Tus, and EF-tu, like Fis, are known DNA binding proteins, substituting Fis sites and Fis protein with binding sites for Tus or EF-tu and Tus and EF-tu proteins or with other protein or fragment thereof, e.g. transactivators like Gal4 or reporters attached to, to characterize interactions of nucleic acids binding sites with these proteins would have been obvious to one of ordinary skill in the art and a reasonable success of synthesizing such nucleic acids would have been highly expected.

Furthermore, it is well-known in the art that a first protein molecule bound to a first binding site on a nucleic acid would block the binding of a second protein molecule to a nearby identical second binding site simply due to the steric effect of the first protein and the nucleic acid. Therefore, a nucleic acid molecule containing two Fis or other binding sites with a close enough spacing so that one Fis or other protein



molecule bound to anyone of the two binding sites would block another protein molecule's binding to the other binding site would have been obvious to one of ordinary skill in the art and a reasonable success of synthesizing such nucleic acids would have been highly expected given the disclosure of Darnell et al. and Hengen et al.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Darnell et al. and Hengen et al. and what is well-known in the art to make and use the instant inventions.

### **Conclusion**

No claim is allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

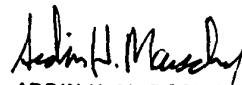
Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D. can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou: sjz   
Patent Examiner

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER